IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN DIVISION

IN RE: Valsartan N-Nitrosodimethylamine (NDMA), and Irbesartan Products Liability Litigation This Document Relates to All Actions	**MDL No. 2875** **Civil No. 19-02875 (RBK/SAK)**

SPECIAL MASTER ORDER NO. 68

Defendants have moved to compel production of testing and other materials in the possession of one of Plaintiffs' expert witnesses on class certification issues, Ron Najafi, Ph.D., an organic chemist and owner of a contract research laboratory, Emery Pharma. Dr. Najafi has opined in this case that "[g]eneric drug manufacturers have an ongoing federal duty of sameness in their products. The generic manufacturer must demonstrate that their active ingredient(s) are the same as the Reference Listed Drug ("RLD") and have identical strength, quality, purity, potency (and where applicable, other characteristics) as the RLD." (Nov. 4, 2021 Expert Declaration of Ron Najafi, ECF Doc. No. 1784-3, at ¶18.)

The RLDs for generic Valsartan are Diovan and Exforge. (*Id.* at ¶14.) Dr. Najafi stated that "[i]t was the drug manufacturers' responsibility to manufacture Valsartan to be the same, chemically equivalent and pass the same quality and purity standards as Diovan and/or Exforge." (*Id.* at ¶15.) He has concluded that

Valsartan containing NDMA or NDEA (nitrosamines) is not the same and/or the chemical equivalent of its RLDs. This conclusion is based upon the assumption that the RLDs "contain zero NDMA and zero NDEA." (Najafi Dep. Tr. at 139-40, ECF Doc. No. 2013-3.)

Defendants have questioned the validity of this assumption on the basis of "Citizen Petitions" filed with the FDA in June of 2019 and March of 2020 by Valisure LLC.[1] It appears that Valisure's testing included the RLDs Diovan and Exforge, and that NDMA was detected in the RLDs. The presence of nitrosamines in the RLDs would undermine Dr. Najafi's opinion that Valsartan containing nitrosamines is not the same as the RLDs.

At the request of Valisure, Dr. Najafi's lab, Emery Pharma, tested some Valsartan pills to validate the results obtained by Valisure with respect to the presence of NDMA and another carcinogenic substance, N,N-Dimethylformamide ("DMF"). At his deposition, Dr. Najafi presented equivocal testimony as to whether his lab had validated the Valisure results, including the results suggesting

[1] In June of 2019, Valisure filed a citizen petition concerning Valsartan, reproduced at ECF Doc. No. 1984-1, and in March of 2020, another citizen petition concerning a different blood pressure medicine, Metformin, reproduced at ECF Doc. No. 2023-2. The Citizens' Petition concerning Valsartan describes Valisure as "an online pharmacy currently licensed in 37 states and an analytical laboratory . . . [whose] mission is to help ensure the safety, quality and consistency of medications and supplements in the market." (ECF Doc. No. 1984-1 at 2.)

nitrosamine contamination of the RLDs.[2] In a post-deposition Declaration, Dr. Najafi stated that his lab did not confirm Valisure's results:

> 5. Valisure, LLC had Emery Pharma test a few valsartan pills for the presence of N,NDimethylformamide ("DMF") and N-nitrosodimethylamine ("NDMA") in a blinded manner and report those results to Valisure, so that Valisure could compare Emery Pharma's testing results with some results previously obtained by testing conducted by Valisure.
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> 7. Emery Pharma was blinded to the manufacturer(s) of the valsartan pills tested for Valisure.

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[2] The following exchange from page 143 of the transcript of Dr. Najafi's deposition indicates that Dr. Najafi's lab did confirm the Valisure testing results:

> Q. Okay. And then you mentioned -- and so essentially I think you just answered what my question was. My question was, did you have the opportunity and did in fact independently corroborate the Valisure data as it related to valsartan nitrosamine quantification?
> A. That's correct. We corroborated their data.

(ECF Document No. 2013-3 at p. 38.) A subsequent exchange suggests that Dr. Najafi's lab did not corroborate Valisure's testing results:

> A. I cannot confirm to you that we corroborated . . . everything that Valisure is presenting in this report vis-a-vis the fact that our name has not been mentioned on this citizen petition. Typically if we do not corroborate something, they shouldn't put our name. If they are not putting our name, it means we didn't have anything to do with these.
> Q. Your assumption that Novartis, Exforge and Diovan formulations contained zero NDMA is not supported in the data from the citizens petition of Valisure, is it?
> A Based on what Valisure is reporting to, you know, I cannot corroborate their data because we didn't do it. This is their data.

(Najafi Dep. at 148; ECF Document No. 2013-3 at p. 139.)

8. Emery Pharma was unaware which manufacturer's valsartan it was testing, or even how many manufacturers' valsartan it was testing.

9. Emery Pharma did not conduct any type of investigation into who manufactured the valsartan pills that Emery Pharma tested for Valisure, because doing so would defeat the purpose of being blinded.

10. Emery Pharma purposefully did not pay attention to any identifying features of the pills or document any identifying features of the pills, because doing so could unblind the study and introduce bias.

11. Emery Pharma did not record in any manner any of the identifying features of the valsartan pills that Emery Pharma tested for Valisure, such as by photograph or a written description.

12. Neither I nor anyone at Emery Pharma have any recollection of any of the identifying features of the valsartan pills that Emery Pharma tested for Valisure.

13. Emery Pharma is not in possession of Valisure's internal testing results that correspond to the valsartan pills Emery Pharma tested in a blinded manner for Valisure.

14. Valisure only gave Emery Pharma a limited number of valsartan pills to test for DMF and NDMA.

15. Emery Pharma tested every valsartan pill that was received from Valisure.

16. Emery Pharma is not still in possession of any of the valsartan pills received from Valisure, because the pills are destroyed via the process that Emery Pharma utilized to test the valsartan pills for DMF and NDMA.

17. Emery Pharma did not test any valsartan pills for the presence of N-nitrosodiethylamine ("NDEA") for Valisure.

18. I have compared the limited valsartan testing results that Emery Pharma performed for Valisure with the numerous valsartan testing results in Valisure's public citizen petition submitted on June 13, 2019.

19. None of the DMF and NDMA levels detected in a Valisure valsartan pill tested by Emery Pharma are remotely close to a DMF and NDMA level reported in Valisure's citizen petition for any Novartis valsartan or Novartis valsartan-HCTZ.

20. Emery Pharma had no involvement with Valisure's internal valsartan pill testing and Emery Pharma does not know the

> details of how Valisure calibrated, validated, or maintained their testing method.

(ECF Doc. No. 2023-3.)

Dr. Najafi's post-deposition Declaration is robust evidence that, even though his deposition testimony suggested that Emery Pharma confirmed Valisure's testing results, no such confirmation occurred. And Plaintiffs have presented compelling arguments that the NDMA contamination reported by Valisure is "the result of a testing error caused by residual NDMA in Valisure's gas chromatography machine after testing samples of pills (from other manufacturers) with NDMA present." (ECF Document No. 2023 at 5.) The fact remains, however, that Dr. Najafi's lab did run tests on valsartan pills, those test results are clearly relevant to his opinions expressed in this case, and Defendants are entitled to see the results of Emery Pharma's testing of valsartan pills.

In his post-deposition Declaration Dr. Najafi asserted that "[a]ll testing results obtained by Emery Pharma for Valisure are considered confidential work product and Emery Pharma cannot disclose the testing results without permission from Valisure." (ECF Doc. No. 2023-3 at ¶21.) There is in place in this action the Amended Confidentiality and Protective Order (ECF Doc. No. 1661) that should assuage the confidentiality concerns expressed by Dr. Najafi while allowing for disclosure of Emery Pharma's testing results. Plaintiffs may produce the Emery Lab testing results subject to that Order.

ACCORDINGLY, IT IS HEREBY ORDERED THAT:

1. Defendants' Motion to Compel the Production of Testing and Other Materials in the Possession of Class Expert, Ron Najafi (ECF Doc. No. 2013) is **GRANTED.**

2. Plaintiffs shall produce, within 14 days, the following materials in the possession, custody, or control of Dr. Najafi or Emery Pharma:

   a) The results of all testing performed by Emery Pharma and/or Valisure on any valsartan drug substance or drug product;

   b) The standard operating procedures, protocols, methods (including validation) governing any such testing;

   c) All reports and data generated related to any such testing;

   d) The standard operating procedures, protocols, and policies related to the sourcing and chain of custody for all samples of valsartan drug substance or drug product received by Emery Pharma, including materials identifying the patient to whom the medication was prescribed, manufacturer, NDC, and batch/lot number;

   e) All correspondence to, from, and among representatives of Emery Pharma and/or Valisure regarding any testing performed on valsartan or the citizen petition submitted to FDA on June 13, 2019; and

   f) All invoices generated by Dr. Najafi and/or Emery Pharma related to

this testing.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master